REMARKS AND ARGUMENTS

Claim Amendments

Without conceding the propriety of the rejections herein and in the interest of expediting prosecution, Applicants amend some claims herein. Applicants amend claims to clarify claimed features. Such amendments are made to expedite prosecution and to more quickly identify allowable subject matter. Such amendments are merely intended to clarify the claimed features, and should not be construed as further limiting the claimed invention in response to the cited references. Furthermore, Applicants add new claims 26-35. All amendments and features of the new claims are fully supported by the Application and therefore do not constitute new matter.

Claim Rejections under 35 USC § 102

Claims 1, 12-15, and 21-25 are rejected under 35 USC § 102(b) as being anticipated by Andrews et al. (US 6,456,955). Applicants respectfully disagree.

Claim 1 describes an exemplary method which includes interconnecting a hub-box to automated devices in a production line via communication links. The hub-box operationally controls and facilitates communication between automated devices and validation of the manufacturing process. The validation includes generating an organized set of documents defining aspects of the process, in conformance with regulatory standards. In addition, a generic interface unit communicatively coupled between the hub-box and an automated device is provided. The generic interface unit includes a plurality of communication links employing different communication protocols, which advantageously allows the generic interface unit to accommodate different types of automated devices from different vendors.

Applicants are unable to find, in Andrews, at least a generic interface unit as recited in claim 1. Andrews merely describes automating the qualification process for chromatographic

systems. *See*, e.g., *Andrews* at Abstract. The automated method is initiated by launching a

Millennium Toolkit that retrieves system information from an Oracle database and creates a

Millennium project. *See*, e.g., *Andrews* at Col. 3 lines 42-49. Active X Data Objects (ADO) are

used to access the data source. However, ADO is merely an *application level interface* to access

data sources (e.g., relational or non-relational databases), and cannot be equated to a generic

interface unit that is communicatively coupled between a hub-box and an automated device.

Moreover, the ADO does not include a plurality of communication links employing different

communication protocols to accommodate different types of automated devices from different

vendors.

In addition, Applicants are unable to find, in Andrews, any disclosure of integrating

automated devices in a production line. In contrast, Andrews merely describes a

chromatography system including a solvent delivery system 12, a sample manager 10, a column

14, a detector 16, and a Data System 18 ("components") for analyzing various products or

pharmaceutical samples. *See Andrews* at, e.g., FIG. 1, Col. 3 lines 34-40. These components do

not appear to be automated devices in a production line. Indeed, *manual intervention* by a

trained operator 100 is required to prepare the chromatography system for qualification to ensure

that the samples, solvents, and the separation column are ready for analysis. *See Andrews* at,

e.g., Col. 2 lines 19-35; Col. 4 lines 6-29.

Claims 12-15 and 21-25 depend either directly or indirectly from independent claim 1.

As discussed above, claim 1 is allowable. It is axiomatic that any dependent claim which

depends from an allowable base claim is also allowable.

For example, with respect to claim 12, Applicants are unable to find, in Andrews, any

disclosure of at least the generic interface unit communicating with the automated device and the

hub-box using first and second communication protocols respectively. In addition, with respect

to claims 13 and 14, Applicants are unable to find, in Andrews, any disclosure of the various first

and second communication protocols as recited in the claims. Further, with respect to claim 15, Applicants are unable to find, in Andrews, any disclosure of the hub-box detecting the first communication protocol and translating instructions or information so that the hub-box can communicate with the automated device.

As shown above, Andrews fails to disclose all of the elements and features of the claims at issue. Accordingly, Applicants respectfully request the withdrawal of the rejections to these claims.

With respect to newly added independent claims 26 and 35, they recite similar limitations as claim 1. These independent claims further require that the automated devices are of a module which forms a stage of a production line. As such, independent claims 26 and 35 as well as their dependent claims are patentable for at least similar reasons as claim 1. Furthermore, some or all these claims may be patentable over the cited art for additional independent reasons.

For example, independent claim 35 and claim 27 require that the automated devices comprise an automated manufacturing device, an automated measuring device and an automated storage device for storage of in-process production material. Applicants submit that this limitation is nowhere found or suggested by Andrews. Therefore, these claims are further patentable over Andrews.

Conclusion

In view of the foregoing, Applicants believe that all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Should the Examiner believe that a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at his number set out below.

Date: May 4, 2010   Respectfully submitted,

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